

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

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IN RE: ZIMMER NEXGEN KNEE IMPLANT	)	
PRODUCTS LIABILITY LITIGATION	)	MDL NO. 2272
	)	
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	)	Master Docket No.: 1:11-cv-05468
This Document Relates To: All Cases	)	
	)	Judge Rebecca R. Pallmeyer
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**PLAINTIFFS' SUPPLEMENTAL REPLY IN OPPOSITION  
TO DEFENDANTS MOTION FOR SUGGESTION OF REMAND**

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Zimmer opposed the creation of this MDL from the outset and this request for remand is another attempt to create a fragmented litigation. However, this attempt is late in time because the JPML has already determined that these cases fall within the scope of the MDL. Plaintiffs have never requested for this Court to expand the MDL. From the beginning, it has always been Plaintiffs position that this MDL consists of two types of products 1) NexGen Flex Total Knee System and 2) NexGen MIS products. These 5 cases were originally transferred to this MDL because the JPML believed they belonged in one of these two categories. Zimmer now wants to interpret the JPML order differently. Zimmer wants to limit the scope of the MDL but fails to offer any additional information now, than at the time of the JPML hearing for this MDL. The complaints in several of the challenged cases contained the exact information that Zimmer wishes to use now to throw these cases out of the MDL. If Zimmer thought it was appropriate to limit the MDL based on the type of failure and to just one MIS design then it should have made those arguments to the JPML a year ago. Nothing slipped through the cracks. This motion is a continuation of Zimmer's consistent effort to limit coordination of these cases and delay litigating the merits of this case.

**I. *Wernette* Does not Reaffirm Zimmers' Position that the MDL is limited to cases Involving the Loosening of the respective MDL Product<sup>1</sup>**

Zimmers' representation that the JPML's Order in *Wernette* was "yet another order [l]imiting the MDL to the loosening of specific components (the "MDL Products")" is wholly inaccurate and misleading. Zimmers' Supplemental Response in Support of its Motion for Suggestion of Remand (Zimmers' Supp. Response), Doc. 537 at 2. The basis upon which the JPML denied the transfer of the *Wernette* case had nothing to do with which component failed or loosened. While Zimmer would like this court to believe that the JPML's ruling in *Wernette* was

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<sup>1</sup> "MDL Product" is being used as an all inclusive term to include the LPS Flex, CR Flex, Gender Solutions LPS Flex, Gender Solutions CR Flex and the MIS tibial component.

somehow related to the two types of cases at issue for remand, *Wernette* did not involve an MIS and it did not involve a Flex femoral component. *Wernette* was a standard NexGen LPS – it was not a Flex. Zimmers' opposition to its transfer was solely on the basis that it was a standard LPS.<sup>2</sup> See Exhibit A attached hereto, Memorandum in Support of Zimmer Entities' Motion to Vacate CTO-56 in Part (Motion to vacate CTO-56), 6:12-cv-03109, Doc 8-1, filed 4/11/2012. Zimmers' brief did not even mention which component failed and the JPML Order did not say that the MDL was limited to cases where the alleged MDL product failed. Zimmers' mere inclusion of the JPML Order in *Wernette* is misleading and wholly unrelated to the issues at hand.

Moreover, Zimmer supports Plaintiffs position that the MDL includes all Zimmer NexGen Flex components and MIS components, irrespective of which component failed, in its Motion to Vacate CTO-56. Zimmer goes as far as to cite to Plaintiffs papers and Plaintiffs argument before the JPML when defining the scope of the MDL. Zimmer concedes in its brief:

From the moment that the plaintiffs proposed centralization, they intended that the MDL would involve only the *NexGen*® Flex femoral components and/or the MIS Tibial Component

See, Ex. A at 2. Zimmer goes on to rely on what Plaintiffs stated in their reply brief before the JPML.

Moreover, in their reply brief in support of the Motion to Transfer, plaintiffs expressly stated that "**all pending actions** involve common questions of fact pertaining to Zimmer's NexGen **High Flex** and MIS implantable knee devices." (Reply in Supp. Mot. for Transfer, Doc. No. 58, p. 1) (emphasis added).

*Id.* at 3. Zimmer even quotes Plaintiffs oral argument from the JPML hearing transcript as to the scope of the MDL.

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<sup>2</sup> Plaintiffs in *Wernette* did not file a Motion in response to the Zimmer' opposition to the transfer of the case.

Lead Counsel, James Ronca, informed the Panel that "each case claim[s] a defect of the **flex aspect** of the NexGen Knee System or the **flex aspect** plus the MIS tibial plate aspect of the NexGen Knee System." (Oral Argument Transcript, attached as Exhibit C, Jul. 28, 2011, p. 4, l. 13-15) (emphasis added).

*Id.* at 4. Zimmer's reasoning for opposing the transfer of *Wernette* is: "the components in *Wernette* lack the very design characteristics at the heart of the plaintiffs' rationale for seeking centralization." *Id.* The design characteristics they are referring to are the Flex and the MIS.

While Zimmer makes inconsistent arguments as to the scope of the MDL before this Court and the JPML, Plaintiffs have consistently claimed that the MDL consists of Zimmer NexGen Flex and MIS products. Zimmer has never stated, until now, that the MDL should be limited to cases where the specific MDL Product loosened. Most importantly, there would be no reason to believe that the JPML intended to limit the MDL to cases where only the MDL Product loosened or failed because no such argument was ever made to the JPML. Further, the JPML does not limit products liability MDLs based on different signature injuries. Such limitations would defy the intended efficiencies of centralized litigation. This is yet another attempt by Zimmer to create a fragmented and splintered litigation.

Zimmer has no basis for claiming that Plaintiffs are seeking to expand the MDL to 21 components. Zimmer's Supp. Response, Doc. 537 at 1. Plaintiffs are not asking for an expansion as to the scope of the MDL. Plaintiffs are merely insisting that Flex and MIS cases remain in the MDL until all common pretrial proceedings are completed and that the cases be remanded at the appropriate time.

## **II. All the Cases have Some Common Factual Issues and will Benefit from Centralization**

All the cases at issue have common factual issues with the remaining MDL cases. *Goldberg*, *Loveday*, *Messina* and *Gaddy* all involve Flex components and the failure in each case is attributed to the Flex design. The defective design of the flex component is the common

factual issue that is at the core of all these cases. Although Zimmer attempts to increase the burden by stating that the common issues must be “material”, they fail to cite any support for that proposition. Zimmers’ Supp. Response, Doc. 537 at 4. As plaintiffs cited in their supplemental brief, the question for the court to consider is: “whether the case will benefit from further coordinated proceedings as part of the MDL.” Plaintiffs Supplemental Brief in Opposition to Defendants’ Motion for Suggestion of Remand (Plaintiffs’ Supp. Brief), Doc. 535, at 6.

These cases will greatly benefit from the pretrial proceedings of this MDL because all the documents relating to the Flex design, including the design concept, engineering, testing and marketing will be produced in the MDL. Further, all the depositions of the Zimmer corporate employees who were in charge of making decisions related to these issues will be deposed in the MDL. Another factor to consider is the science and experts that will be needed. The parties will likely retain experts such as biomechanical engineers, kinetic engineers, surgeons and tribologists to opine on the design flaws of the Flex design. These experts would be the same irrespective of whether there was tibial loosening or femoral loosening.

This same overlap has already been seen in the design teams for the 5950 and the 5954. In a 10 or 11 person team, there are 8 people who are the same. This is because the same considerations such as surgeon visibility and MIS technique have to be taken into consideration when designing an MIS tibial plate. Moreover, experts retained for the MIS cases will likely be the same regardless of whether it’s a 5950 or a 5954. Some of the experts may even overlap with the experts retained for the Flex cases. Despite Defendants representation that *Krammes* is the only 5954 case in the MDL with a recalled lot, Plaintiffs are aware of at least one other case where the Plaintiff received a recalled 5954.<sup>3</sup> See Zimmer’s Supp. Response, Doc 537, at 5.

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<sup>3</sup> To date, Plaintiffs are aware of 24 5954 MIS cases, however Plaintiffs do not have access to the product identification numbers in all these cases to determine if they were part of the recall.

Donovan Bray received bilateral knee replacements and received one of the recalled 5954 MIS tibial plates along with a LPS Flex femoral component in his left knee which failed and required revision surgery. Since this case involves both a Flex and a recalled MIS both components are at issue and will remain in the MDL. Thus, *Krammes* would benefit from remaining in the MDL and the common pretrial proceedings involving the 5954 MIS. There are enormous efficiencies gained through centralized management of these cases.

Zimmers' naive statement that multiple schedules or tracks would not be needed if the cases were as similar as Plaintiffs' claim and the efficiencies were as real, is ignorant of multiple JPML orders and many successful products liability MDLs. Zimmers' Supp. Response, Doc 537, at 5. The JPML has repeatedly stated in one transfer order after another in products liability MDLs that the "transferee court can employ any number of pretrial techniques -- such as establishing different discovery and/or motion tracks -- to efficiently manage this litigation." See *In Re: Denture Cream Prods. Liab. Litig.*, 624 F.Supp.2d 1379, 1381 (J.P.M.L 2009); *In Re: Kugel Mesh Hernia Patch Prods. Liab. Litig.*, 493 F.Supp.2d 1371, 1374 (J.P.M.L 2007); *In Re: Gadolinium Contrast Dyes Prods. Liab. Litig.*, 536 F.Supp.2d 1380, 1382 (J.P.M.L 2008); *In Re: Vioxx Prods. Liab. Litig.*, 360 F.Supp.2d 1352, 1354 (J.P.M.L 2005); *In Re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.*, 787 F.Supp.2d 1358, 1360 (J.P.M.L 2011); and *In Re: Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 780 F.Supp.2d 1379, 1381 (J.P.M.L 2011) (The JPML directly addressed the issue where there may be some individual discovery stating: "Transferee Judges can accommodate common and individual discovery tracks, gaining the benefits of centralization without delaying or compromising consideration of claims on their individual merits.")

This is no different than in the Yaz MDL where there were three types of cases that evolved, gallbladder, pulmonary embolism and thromboembolic. All three injuries were

allegedly caused by the same defective product, Yaz/Yasmin. Of course there may have been unique individual circumstances in some cases where there may have been more than one possible cause for that particular injury but those cases still benefited greatly from the common pretrial proceedings surrounding the defective product. Here, we have an MDL where there are two alleged defective products – 1) the Flex components and 2) the MIS tibial components. The defective Flex components can cause loosening of the tibial tray or the femoral component. Thus, if through the course of discovery this Court determines that these two types of cases (Flex/femoral loosening and Flex/tibial loosening) have certain dissimilar aspects so that they would benefit from different tracks, the MDL has this management mechanism at its disposal. This is frequently used in products liability MDLs and is encouraged by the JPML as an efficient way to manage these types of litigations.

### **III. Plaintiffs Theory that the Flex Design can cause Tibial Loosening is not Conclusionary**

While this is an issue that will likely be decided at the time of *Daubert* hearings, Plaintiffs have a plausible theory rooted in scientific literature and Zimmer's own documents. Tibial loosening is a concern that Zimmer clearly took into consideration with the design of the Flex. In addition to the design rationale cited throughout Plaintiffs Supp. Brief, there are many other Zimmer documents that confirm tibial loosening was a concern with the Flex design.

In a document called "Failure Mode Effects Analysis Form" for project name "Flex Knee" it lists a number of potential failure modes. Z007083-7087. For example, potential failure mode number 4 is identified as "posterior location of the tibio-femoral contact as higher flexion angles results in anterior lift up of the articular surface" and the possible effect is listed as "repeated anterior lift up could eventually compromise the locking mechanism". Z007086. Hand written on the last page of this document under failure mode number 5 it says "Failure Mode #6 Tibial Fixation". Z007087. Since we have not completed discovery or taken a

deposition on this issue yet we do not know exactly what this means. However, when put into context with the rest of the document it seems to suggest an additional failure mode associated with the flex design – tibial loosening. In another Zimmer document titled “Technical Memorandum 1306.02” which measure the micromotion of the tibial plate during high flexion in the CR and CR-Flex it states in the introduction “when considering the factors related to high flexion activities, the possibility of anterior lifting of the tibial plate must be included.” Z004844. For Zimmer to say that any connections between the flex designs causing an increased risk of tibial loosening are based on mere lawyers’ conclusions is disingenuous. See, Zimmers’ Supp. Response, Doc. 537 at 5.

Further, when citing to the *Toshiro* and *Barrack* studies Zimmer failed to provide the court with the exact quote that Plaintiffs provided to Defendants in an email after the June 1<sup>st</sup> hearing. Zimmers’ Supp. Response, Doc. 537 at 6-7. At the Defendants request, Plaintiff sent an email Defendants with the references to the two studies and an excerpt of the follow quote from *Toshiro*:

However, we should be cautious regarding the medial and lateral shift of the femoral or tibial components. Our results showed the tibial components in the MIS group shifted to a more medial position and the shift varied more widely than in the standard group. This tendency was seen mainly in our early MIS TKAs. Tibial component medialization greater than 3 mm also was reported in four of 30 quadriceps-sparing TKAs and three of 30 mini-subvastus TKAs.<sup>1</sup> Although tibial components in our cases ran off the medial edge only 1 to 2 mm at most, an excessive medial shift of the tibial components theoretically could increase the medial tightness or increase the risk of loosening over the long term. We suspect the medial shift of the tibial components in the MIS TKA could have resulted from difficulty in observing the lateral tibial plateau or from difficulty in clearing the lateral femoral condyle with a standard tibial implant. Surgeons should be aware of this issue.<sup>4</sup>

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<sup>4</sup> *Toshiro, Y., et al.*, Minimally Invasive Versus Standard Approach in Total Knee Arthroplasty, [Clinical Orthopaedics And Related Research], Number 463, pp. 144–150, 149.

See Ex. B, Email from Jim Ronca dated June 27, 2012. Plaintiffs were merely referencing one study that came to mind at the time of argument before this court on June 1, 2012. It would be premature to cite to all the world's literature on this issue at this time without the full benefit of discovery and Zimmer's own studies on this issue.

Plaintiffs have a more than plausible theory that the Flex design can cause tibial loosening, which is support by both medical and scientific literature and Zimmer's own documents. This has remained a consistent theory from the beginning of this litigation and at the time that these cases were transferred.

#### **IV. Conclusion**

Plaintiffs respectfully request that this court deny Zimmer's motion for a suggestion of remand as to all five of these cases, *Goldberg*, *Loveday*, *Messina*, *Gaddy* and *Krammes* because they all fall within the scope of this MDL, or, in the alternative, defer this Motion until a more appropriate time and allow for additional discovery and depositions to take place on these issues.

Dated: July 10, 2012

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on July 10, 2012, the foregoing Plaintiffs' Supplemental Reply In Opposition To Defendants Motion For Suggestion Of Remand was filed electronically. Parties may access this filing through the Court's system.

/s/ James R. Ronca